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Chip E. Williams, Esq.
Pullin Fowler & Flanagan, PLLC
Legacy Plaza, Suite 103, 300 N. Kanawha Street
Beckley, WV 25802

Expert Report of Dr. Bryan D. Hardin in the matter of
Boone et al v. State of West Virginia, Department of Health and Human Services

I have been asked to provide an expert opinion regarding the claims of adverse human health effects from alleged exposure to molds in the matter of Boone et al v. State of West Virginia, Department of Health and Human Services. I have extensive general knowledge in the field of toxicology and specific knowledge of the effects of mycotoxins from mold in indoor environments. The following report outlines my relevant qualifications and opinions.

QUALIFICATIONS

I am a Fellow of the Academy of Toxicological Sciences and a member of the American College of Occupational and Environmental Medicine, the American College of Toxicology, the American Industrial Hygiene Association, the Society of Toxicology, and the Teratology Society. I received a Bachelor of Science degree in Mathematics in 1966, a Bachelor of Science degree in Zoology in 1970, and a Master of Science degree in Zoology in 1972, all from the University of Oklahoma; in 1983 I received a Ph.D. in Environmental Health Sciences from the University of Cincinnati, Division of Graduate Studies and Research. I served 28 years as a commissioned officer in the United States Public Health Service (USPHS) assigned to the National Institute for Occupational Safety and Health (NIOSH), including nine years research experience in the NIOSH Experimental Toxicology Branch. At the time I left the USPHS in July 2000, I was the Deputy Director of NIOSH and Assistant Surgeon General in the USPHS. Currently, I am a Principal of Veritox, Inc., which is a health-based consulting company focusing on toxicology and industrial hygiene. I have attached a true and correct copy of my curriculum vitae to this report in Appendix A.

RECORDS REVIEWED

I reviewed the following case-specific materials in support of the preparation of my opinions relating to the claims in this matter:

- Summons
- Complaint
- Plaintiff's Preliminary Designation of Expert Witnesses
- Deposition of Bill Adamy 9/27/05 and exhibits
- Deposition of Blair Thrush
- Deposition of Dominic Gaziano and exhibits
- Deposition of David Goetz
- Deposition of Melissa Abbott
- Deposition of John Keeling
- Deposition of Edward N. Light
- Deposition of Jonathan Bernstein (Volumes 1 & 2)
- Reta L. Boone Medical Record Summary
- Elizabeth Cochran Medical Record Summary & Selected Records
- Sally Conley Medical Record Summary & Selected Records
- Mary Hall Medical Record Summary & Selected Records
- Evelyn Jordan Medical Record Summary & Selected Records
- Arletta Mathes Medical Record Summary & Selected Records
- Margaret McCourt Medical Record Summary & Selected Records
- Joy Skeens Medical Record Summary & Selected Records
- Linda Smith Medical Record Summary & Selected Records
- "Plaintiff Doctor's Depositions" September 2007 (Likely exhibits from the depositions of Drs Thursh, Gaziano, Guberman, Grady, Goetz, and Dee. Includes IMEs for Elizabeth Cochrane, Sally Conley, Mary Hall, Evelyn Jordan, Arletta Mathes, Joy Skeens, and Linda Smith.)
- Department of Health and Human Resources Indoor Air Quality Evaluation of DHHR Office Webster Springs, Report dated 8/2/02 (inspection 6/27/02)
- Letter from Rock Branch Mechanical, Inc. regarding HVAC inspection dated 10/16/02
- Report of Findings, Indoor Air Quality Investigation of Department of Health and Human Resources (Webster Springs, WV) by MSES Consultants, dated 10/22/02 (inspection 10/2/02)
- Follow-up Report, Site Investigation of Basement Area and Attic Area of Department of Health and Human Resources (Webster Springs, WV) by MSES Consultants, dated 11/27/02 (inspection 10/31/02 and 11/11/02).

- American Clean Air Report on air duct cleaning project at Webster Springs DHHR Offices, dated 2/3/03
- INX Laboratories Yeast/Mold/Bacteria Screening Results, dated 4/28/03 and 5/2/03 (collection date 4/21/03)
- Report of Findings, Follow-Up Investigation of Webster Springs Department of Health and Human Resources by MSES Consultants, dated 6/2/03 (inspection 4/30/03 and 5/9/03)
- Final Report, Follow-up Canister Analysis Results of Department of Health and Human Resources (Webster Springs, WV) by MSES Consultants, dated 7/2/03 (samples collected by DHHR personnel on 6/2/03)
- Columbia Analytical Services, Inc., VOC sample report (non-dated)
- NIOSH Health Hazard Evaluation Report, dated March 2006 (inspection 9/03 and 4/04).

BASIS OF OPINIONS

The basis for my opinions in this case includes my education, training in basic science, experience in toxicology in general and as specifically related to mycotoxin exposure, ongoing review and analysis of published literature on the effects of mycotoxins on a broad range of mammalian species including humans, and general knowledge of the adverse effects of chemicals on mammalian species including humans. This training, experience, and study of the published literature include in-depth knowledge of inhalation toxicology, which includes normal respiration and adverse respiratory effects resulting from exposure to chemicals.

COMPLAINT

Based on my review of the above records, it is my understanding that the plaintiffs in this matter (Reta Boone, Elizabeth Cochrane, Sally Conley, Mary Hall, Evelyn Jordan, Arletta Mathes, Lynn McCourt, Joy Skeens, and Linda Smith) claim to have been “injured and/or made ill” as a result of “toxic environmental conditions” at their workplace at the Webster Springs DHHR office, 110 North Main Street, Suite 201.¹

ANALYSIS OF TOXICOLOGICAL ISSUES

Toxicologists have reached a generally-accepted consensus on the methodology and criteria that must be taken into account in reaching any conclusions as to whether exposure to a chemical has caused an injury to an individual. There are several criteria that must be

¹ Complaint

met in order to establish that exposure to a chemical has caused an injury. If any one of the following criteria is not met, causation cannot be established.²

- a. The chemical(s) in question must first be present.
- b. Toxicological or epidemiological studies must show that the chemical(s) in question are able to cause the claimed adverse effect.
- c. Exposure of an individual to the chemical(s) must be in sufficient quantities and for a sufficient length of time to cause the claimed adverse effect.
- d. Exposure to the chemical(s) must precede the claimed adverse effect within an appropriate time frame specific to the development of the individual chemical's effect.
- e. If the above criteria are met then alternative known causes of the claimed adverse effect must be considered and weighed against the probability that the chemical(s) in question caused or contributed to the adverse effect.

As a toxicologist, I used the above criteria to determine whether or not the plaintiffs could have been adversely affected mold or by other claimed "contaminants" at the Webster Springs DHHR office.

a. Were the chemicals in question present?

Mold and Mycotoxins

Molds are fungi, part of the Kingdom Mycota, which comprises a diverse group of organisms that evolved over 400 million years ago.³ Mold and mold spores are everywhere around us, and have always been a part of our environment. The air we breathe is a virtual jungle of fungal spores, and we routinely encounter mold spores as part of everyday life both indoors and outdoors.⁴ Spore levels may vary seasonally, but some spores are always present. In one large national dataset of cultured air samples collected from 1996 to 1998, median seasonal counts outdoors in the northeastern United States (a sampling region including West Virginia) ranged from about 200 CFU/m³ (winter) to about 600 CFU/m³ (summer); peak spore concentrations were as high as 3000 CFU/m³ (winter) and 6000 CFU/m³.⁵ In another survey of background spore levels, outdoor spore trap counts in

² Federal Judicial Center (2000). Reference Manual on Scientific Evidence, Second Edition. (Federal Judicial Center), 639 pages. Federal Judicial Center.

³ Sherwood-Pike, M. A. and Gray, J. Silurian fungal remains: probable records of the class Ascomycota. *Lethaia* 18, 1-20. 1985. 1985.

⁴ Solomon, W. R. Assessing fungus prevalence in domestic interiors. *J Allergy Clin Immunol* 56(3), 235-242. 1975.

⁵ Shelton, B. G., Kirkland, K. H., Flanders, W. D., and Morris, G. K. Profiles of airborne fungi in buildings and outdoor environments in the United States. *Appl Environ Microbiol* 68(4), 1743-1753. 2002.

Washington, DC, ranged from 90 to 3,690 spores/m³ in March-June 2001, and from 787 to 13,678 spores/m³ in September-December 2001.⁶

The DHHR office was inspected and sampled for mold by various agencies over a multi-year period:

- On October 2, 2002, MSES Consultants conducted a site inspection at the DHHR offices and collected surface wipe samples for bacteria and mold; samples were analyzed by Pure Earth Environmental Lab, Inc. The primary spores found were *Pseudomonas*, *Bacillus*, *Yeasts*, and *Cladosporium*.⁷
- MSES Consultants conducted follow up evaluations of the basement on October 31, 2002, and of the attic spaces and air handling system on November 11, 2002. Water stains were identified on the rubber roof seal. Resealing was recommended. No visible mold growth was seen in the attic or crawlspace. A wipe sample was collected above the ductwork following visual inspection of the return air plenum. Sample analysis found the presence of *Actinomyces* bacteria and *Penicillium* and *Ulocladium* fungi.⁸
- On April 21, 2003, American Clean Air collected samples for mold and bacteria analysis by INX Laboratories.⁹ Sampling results indicated the presence of the fungi *Cladosporium* (10 CFU/plate), *Aurobasidium pullulans* (3 CFU/plate), and *Acremonium* (1 CFU/plate) and the bacteria *Bacillus* (2 CFU/plate) and *Staphylococcus* (5 CFU/plate).
- On April 30, 2003, MSES conducted a follow-up site inspection and collected cultured air samples for mold and bacteria.¹⁰ The maximum indoor spore concentration was 364 CFU/m³ in the social services area; the outside concentration was 6,026 CFU/m³. The maximum indoor bacterial count was 116 CFU/m³; the outdoor bacterial concentration was measured 232 CFU/m³.
- On September 11-12, 2003, NIOSH conducted a walkthrough of the building and collected non-cultured air samples for mold. No obvious sources of mold or water intrusion were observed. The maximum indoor spore concentration measured by NIOSH during sampling conducted on September 11, 2003, was 386 spores/m³ in the cubicle near the computer room. The primary indoor species were *Alternaria* (267 spores/m³), *Penicillium* (107 spores/m³), and *Cladosporium* (107 spores/m³). The measured outside concentration was 12,608 spores/m³ on the same day.¹¹
- On April 12-14, 2004, NIOSH conducted a walkthrough of the building and collected a Bio-Tape surface sample (Zefon). Water incursion, visible mold, and

⁶ Gots, R. E., Layton, N. J., and Pirages, S. W. Indoor health: background levels of fungi. American Industrial Hygiene Association Journal 64(4), 427-438. 2003.

⁷ Report of Findings, Indoor Air Quality Investigation of Department of Health and Human Resources by MSES Consultants, dated 10/22/02 (inspection 10/2/02).

⁸ Follow-up Report, Site Investigation of Basement Area and Attic Area of Department of Health and Human Resources (Webster Springs, WV), by MSES Consultants, dated 11/27/02 (inspection 10/31/02 and 11/11/02)

⁹ INX Laboratories Yeast/Mold/Bacteria Screening Results, dated 4/28/03 and 5/2/03

¹⁰ Report of Findings, Follow-Up Investigation of Webster Springs Department of Health and Human Resources by MSES Consultants, dated 6/2/03 (inspection 4/30/03 and 5/9/03)

¹¹ NIOSH Health Hazard Evaluation Report, dated March 2006 (inspection 9/03 and 4/04)

musty odors were noted in the basement. Musty odors were noted in the entry area of the building, the elevator, and the south stairwell. Odors from the restrooms were noted on the second floor.¹²

The ubiquitous presence of mold in air and on building materials makes it impossible to construct or maintain a building that is mold-free using standard building design and construction techniques. Even if construction of a mold-free building space were possible, the maintenance of a mold-free environment under normal conditions would be impossible, as many species of mold are naturally present in the air and on and in human bodies, potted plants, and on foods such as fresh fruit and cheeses. The most significant source of mold spores indoors is the outdoor air¹³ and a mold-free building will no longer be mold-free once a door or window is opened or a person enters. The question is whether there is an increased risk of adverse health effects from indoor levels as opposed to outdoor levels.

Mycotoxins are fungal metabolites that in sufficient dose may be toxic to humans or animals. They are sometimes produced as by-products of mold's biological processes but they are not required to maintain the life of the mold. Furthermore, an exhaustive review of the scientific literature demonstrates agreement that mycotoxins are only sometimes produced by molds; they are not always produced and cannot be assumed to be present based on the fungal species present.¹⁴ No records of mycotoxin sampling at the property were provided for my review.

Additionally, as discussed in section (c) of this report, dose-response is the most fundamental principal of toxicology. A toxic response follows only if a sufficiently high dose is absorbed, and there are no data to suggest that the plaintiffs could have received a toxic dose of any mycotoxin while working at DHHR.

Finally, the musty odor associated with mold comes from volatile compounds generated as the mold grows. The odor of these compounds, which are not mycotoxins, may be

¹² NIOSH Health Hazard Evaluation Report, dated March 2006 (inspection 9/03 and 4/04)

¹³ Solomon, W.R. 1975. *loc. cit.*

¹⁴ ACMT. American College of Medical Toxicology Comment -- Institute of Medicine Report on Damp Indoor Spaces and Health. 2006. 2006. ; Burge, H.A. (2001). The fungi. In Indoor Air Quality Handbook (Spengler, J. D., Samet, J. M., and McCarthy, J. F.), 45.1-45.33. McGraw Hill.; Fung, F. and Clark, R. F. Health effects of mycotoxins: a toxicological overview. J Toxicol Clin Toxicol 42(2), 217-234. 2004. ; Halsall, W.J., Isham, N.C., and Ghannoum, M.A. (2007). Mycotoxins. (Murray, P. R., Baron, E. J., Jorgensen, J. H., Landry, M. L., and Pfaller, M. A.), 9th ed., 1928-1935. ASM Press, American Society for Microbiology, 1752 N Street, NW, Washington DC 20036-2904.; Rao, C.Y. (2001). Toxicogenic fungi in the indoor environment. In Indoor Air Quality Handbook (Spengler, J. D., Samet, J. M., and McCarthy, J. F.), 46.1-46.17. McGraw Hill, New York, NY.; Ren, P., Ahearn, D. G., and Crow, S. A. Comparative study of *Aspergillus* mycotoxin produced on enriched media and construction material. J Industrial Microbiol Biotechnol 21, 209-213. 1999. ; Tuomi, T., Reijula, K., Johnsson, T., Hemminki, K., Hintikka, E. L., Lindroos, O., Kalso, S., Koukila-Kahkola, P., Mussalo-Rauhamaa, H., and Haahtela, T. Mycotoxins in crude building materials from water-damaged buildings. Appl Environ Microbiol 66(5), 1899-1904. 2000.

annoying, but they are not toxic at concentrations encountered in the indoor built environment.¹⁵

Other Compounds

Worker complaints of runny eyes and noses apparently began in the spring of 2002.¹⁶ Over succeeding months, additional symptoms were mentioned and attributed to freon leaks and various odors.¹⁷ In addition to the sampling previously described for mold, the DHHR office was inspected and sampled for environmental conditions and chemicals by various agencies over a multi-year period:

- On June 27, 2002, the State of West Virginia, Department of Health and Human Resources conducted an indoor air quality evaluation at the DHHR office and measured carbon dioxide (870 ppm maximum), relative humidity (51.3% maximum), temperature (90.5F maximum) and carbon monoxide (not detected).¹⁸
- October 2, 2002, MSES consultants conducted a site inspection at the DHHR offices on and measured carbon dioxide (608 ppm maximum), temperature (73.3 maximum), and relative humidity (52.6%).¹⁹
- On October 13, 2002, Rock Branch Mechanical inspected the HVAC systems and found no evidence of a Freon leak or other source of contamination.²⁰
- On April 30, 2003 and May 9, 2003, MSES conducted a site inspection and collected air samples for VOC analysis (including formaldehyde) by Columbia Analytical Services.²¹ However, all air sampling results for VOCs were well below established criteria levels or the level of detection.
- On June 2, 2003, DHHR Personnel collected air samples for VOC analysis by Columbia Analytical Services. MSES reviewed the analysis results. All air sampling results for VOCs were well below established criteria levels or the level of detection.²²
- On September 11-12, 2003, NIOSH conducted a walkthrough of the building and measured temperature (74.5F maximum), relative humidity (45.2% maximum), and carbon dioxide measurements (1095 ppm maximum, average 550-650 ppm) and

¹⁵ Korpi, A., Kasanen, J. P., Alarie, Y., Kosma, V. M., and Pasanen, A. L. Sensory irritating potency of some microbial volatile organic compounds (MVOCs) and a mixture of five MVOCs. Arch Environ Health 54(5), 347-352. 1999.

¹⁶ Deposition of Bill Adamy (5:4-5:16)

¹⁷ Report of Cologne/Perfume-Cleaning procedures for Webster County District, dated 10/4/02

¹⁸ Department of Health and Human Resources Indoor Air Quality Evaluation of DHHR Office Webster Springs, report dated 8/2/02 (inspection 6/27/02)

¹⁹ Report of Findings, Indoor Air Quality Investigation of Department of Health and Human Resources by MSES Consultants, dated 10/22/02 (inspection 10/2/02)

²⁰ Letter from James Clark of Rock Branch Mechanical, Inc. to Randy of City of Webster Springs, dated 10/16/02

²¹ Report of Findings, Follow-Up Investigation of Webster Springs Department of Health and Human Resources by MSES Consultants, dated 6/2/03 (inspection 4/30/03 and 5/9/03)

²² Final Report, Follow-up Canister Analysis Results of Department of Health and Human Resources (Webster Springs, WV) by MSES Consultants, dated 7/2/03 (samples collected by DHHR personnel 6/2/03)

collected air for VOC analysis. Odors from cleaning supplies were reportedly apparent. All air sampling results for VOCs were well below established criteria levels or the level of detection²³

- On April 12-16, 2004, NIOSH conducted a walkthrough of the building and collected temperature, relative humidity, carbon dioxide, and total particulate measurements, and air samples for VOC analysis. Odors from the restrooms were noted on the second floor. All air sampling results for VOCs were well below established criteria levels or the level of detection.²⁴

b. Do toxicological or epidemiological studies show that the chemicals in question are able to cause the claimed adverse effect?

I reviewed the medical records and independent medical examinations provided for the plaintiffs:

Reta Lorene Boone

Ms. Boone reported a workers' compensation injury on 9/27/02. She reported that at the time of the injury, she became severely ill with eye irritation, body aches, throat irritation and sinus infection.

In two Independent Medical Evaluations, dated 5/11/05 and 8/3/05, Ms. Boone complained of sinus infection since fall 2002, burning and watering eyes, nasal drainage, sore throat, sinus pressure, body aches, bleeding and recurrent bronchitis, poor memory and concentration (which she states may be due to age), headaches (which she said may be due to stress at work), fatigue, blurry vision, shortness of breath, chest pain or pressure at night, dizzy spells when standing up, long-standing dry skin (which she associates with winter weather), and emotional symptoms. Ms. Boone was reportedly vague about respiratory symptoms.^{25,26}

The IME physical exam on 5/11/05 and an additional physical exam on 7/21/05 reported no abnormalities and the chest and lungs were normal.²⁷ No allergy testing was reported.

Dr. Martin does not believe that "any work-related condition can be alleged for this claimant." Dr. Gaziano identifies her as having "sick building syndrome" but believes she can continue working and does not believe there is any permanent impairment related to her exposure.

²³ NIOSH Health Hazard Evaluation Report, dated March 2006 (inspection 9/03 and 4/04)

²⁴ NIOSH Health Hazard Evaluation Report, dated March 2006 (inspection 9/03 and 4/04)

²⁵ Independent Medical Evaluation of Reta Boone: Christopher Martin, MD, MSc, WVU Dept. of Occupational Medicine 5/11/05 Exhibit 5 (4 pages)

²⁶ Independent Medical Evaluation of Reta Boone: D. Gaziano, MD, Chest Medical Services, Inc. 8/3/05 (000590-591)

²⁷ Medical Records of Reta Boone: D. Gaziano, MD, Chest Medical Services, Inc. 7/21/05 (000592-599)

Elizabeth Cochran

According to her Independent Medical Exam, Ms. Cochran reported that in the fall of 2002, she started developing symptoms such as shortness of breath, headaches, chest discomfort, muscular cramping, nausea, and rashes. During the physical exam portion of her IME on 8/10/05, no abnormalities or signs of impairment were noted. No allergy testing was reported.²⁸

Sally Conley

According to her Independent Medical Examination, Ms. Conley reported that in the first week after returning to work at the DHHR building on 3/17/03 she experienced itching skin without rash, non-productive cough, dry mouth, shortness of breath, wheezing, chest tightness, and awakening from sleep with shortness of breath. In 5/03 she was reportedly diagnosed with occupational asthma by Dr. Osborne (records not provided). In the IME physical exam on 9/21/05, no physical abnormalities were noted, although Ms. Conley reported she still had intermittent shortness of breath and chest tightness with exertion when she is around truck fumes, and especially while in the DHHR building. She reported she had no further pruritus or rash since the first month after the exposure. No allergy testing was reported.²⁹

A pulmonary function test on 9/26/05 found lung volumes close to 100% predicted with no evidence of bronchospasm or acute respiratory illness present.³⁰ A chest X-ray on 9/26/05 also indicated a normal chest.³¹

Mary Hall

According to her Independent Medical Exam, Ms. Hall reported that symptoms of nose and mouth irritation, burning sensation in eyes, sinus congestion, and runny nose began in summer 2002. During the physical examination portion of her IME on 2/1/06, no abnormalities were reported, although Ms. Hall reported she has had problems with recurrent sinus and ear infections, as well as runny nose and congestion that she attributes to environmental exposure in her workplace. No allergy testing was reported.³²

²⁸ Independent Medical Evaluation of Elizabeth Cochran: Joseph E Grady II, MD, CIME, Tri-State Occupational Medicine, Inc., 8/10/05 (000009-013)

²⁹ Independent Medical Evaluation of Sally Conley: Bruce Guberman, MD, Tri-State Occupational Medicine, Inc. 9/21/05 (000530)

³⁰ Pulmonary Function Test of Sally Conley: Bruce Guberman, MD, Tri-State Occupational Medicine, Inc., 9/26/05 (000535-536)

³¹ Chest X-ray of Sally Conley: Eli Rubenstein, MD, Eli Rubenstein, MD, Inc. 9/26/05 (000538)

³² Independent Medical Evaluation of Mary Hall: Joseph E Grady II, MD, CIME, Tri-State Occupational Medicine, Inc., 2/1/06 (000009-013)

Evelyn Jordan

According to her Independent Medical Exam, Ms. Jordan's chief complaint was exposure to molds at work. Ms. Jordan moved into the DHHR building in November 1994 and reported that she began to experience "non-stop" sinus infections beginning in the mid to late 1990s. Ms. Jordan reported a workers' compensation claim on 9/25/02. She reported that at the time of the injury, she experienced shortness of breath, wheezing, and a rash. In addition, she stated her tongue appeared scalded for 1 year beginning in 2002, which was treated for infection. In 9/02 she was reportedly diagnosed with allergic rhinitis, non-allergic rhinitis, environmental allergies, and asthma. During the IME physical exam on 9/21/05, Ms. Jordan reported that she continues to have sinus problems with intermittent ear infections and still experiences wheezing and shortness of breath with exertion or upper respiratory illnesses, when the weather is cold, hot, or humid, and when she is around dust or perfumes. Ms. Johnson indicated that episodes of lip burning and tingling that occurred while working resolved after she retired (August 2005) The IME physical exam on 9/21/05 noted no physical abnormalities. No allergy testing was reported.³³

Arletta Mathes

According to her Independent Medical Exam, Ms. Mathes reported that she began having symptoms of burning sensation in her eyes and runny nose and sinus and facial pain, beginning sometime around September 2002. Symptoms seemed to be associated with work. Ms. Mathes reported that she has current problems with facial pain and some reddish discoloration of her face and rare cases of oral blistering. Other symptoms include bloodshot eyes, headaches, enlargement of lymph nodes in her neck, dizziness, some visual problems, eye itching and some neck pain. The IME physical exam on 2/1/06 found no abnormalities. No allergy testing was reported.³⁴

Margarette McCourt

In April 2001, Ms. McCourt's internist indicated a history of allergic rhinitis and a CT scan that showed pneumatized sinuses; therefore, she was referred to an allergist.³⁵ Upon evaluation in May 2001, Ms. McCourt reported sinus congestion and headaches "all her life", post nasal drip year round, and frequent sinus infections. Her medical exam revealed acne scars, some palmar erythema, slightly inflamed nasal mucosa, slightly decreased

³³ Independent Medical Examination of Evelyn Jordan: Bruce Guberman, MD, Tri-State Occupational Medicine, Inc., 9/21/05 (000060-065)

³⁴ Independent Medical Examination of Arletta Mathes: Joseph Grady II, MD, CIME, Tri-State Occupational Medicine, Inc. 2/1/06

³⁵ Medical Records of Margarette McCourt: Paul Conely, DOSummersville Outpatient Center, 4/5/01 (000150)

breath sounds, dry eyes, congested ears, post nasal drip and occasional cough. Ms. McCourt's allergy skin tests were negative (including those for mold) except for histamine (2+) and "Tree 5" and "Tree 6" (which were marked with an "X"). Ms. McCourt was diagnosed with facial pain, headaches, and nasal congestion.³⁶

Joy Skeens

Ms. Skeens reported a workers' compensation injury on 10/30/02. According to her Independent Medical Exam, Ms. Skeens reported that after 1.5 weeks of working at DHHR in Webster Springs she experienced shortness of breath, cough, runny/sore nose, rash with hives primarily from her waist up, blistering of her lips, and yeast infection on her tongue and in her ear. She also reported that she saw a nurse practitioner two weeks later regarding her symptoms and was told she had asthma. Ms. Skeens reported she developed wheezing by June 2003. During the IME physical exam on 8/15/05 Ms. Skeens complained of breathing problems and reported that she still feels short of breath walking up stairs or a hill, or when waking from sleep. She also reported mild pedal edema, chronic non-productive cough, and increased wheezing when weather is hot or damp, when she is around smoke or cleaning products, or when she has an upper respiratory illness. Ms. Skeens stated that the yeast infection resolved and the rash improved one month after she stopped working at the facility (October 2003). The IME exam of 8/15/05 noted no physical abnormalities.³⁷

A pulmonary function test on 8/18/05 indicated normal pulmonary function with no evidence of bronchospasm or respiratory illness.³⁸

Dr. Guberman indicated she required "ongoing medical treatment and medication because of her occupational illness of occupational asthma".

Linda Smith

Ms. Smith reported a workers' compensation injury on 9/5/02 as a result of an injury while working at DHHR in Webster Springs. Her complaints included chest pain, headache, pharyngitis, a burning sensation in her face, eyes and throat, and a rash on her face. After following up with a doctor, Ms. Smith states she was told she has asthma, chronic sinusitis, and allergies to various insects, plants, and dusts.

³⁶ Medical Records of Margarette McCourt: Blair Thrush, MD, Thrush Clark Allergists, PLLC 5/4/01 (000144-149)

³⁷ Independent Medical Examination of Joy Skeens: Bruce Guberman, MD, Tri-State Occupational Medicine, Inc.

³⁸ Pulmonary Function Test of Joy Skeens Bruce Guberman, MD, Tri-State Occupational Medicine, Inc. 8/18/05 (RBM 0440-441)

The available medical records for Ms. Smith begin in 2003. IgE tests on 6/6/03 indicate allergy for *Dermatophagoides pteronyssinus* and *D. farinae* (dust mites), but not *Penicillium notatum*, *A. Alternata*, or other substances tested.³⁹

On 8/26/03, Ms. Smith saw David Goetz, MD for evaluation of environmentally induced bronchospasm, rhinitis, arthralgias, as well as low IgM on laboratory studies. She reported that seven years ago she developed rhinorrhea, itchy nose, itchy watery eyes, sneezing, nasal congestion, post nasal drainage, sinus pressure, throat clearing, and headache. She reported that 1 year ago she began to experience nighttime cough, exercise associated cough and wheezing, as well as “work associated cough and chest discomfort”. Skin tests on 8/26/03 were reported to be strongly positive for cockroach, house dust mites, and lady bug and positive for several tree pollens. Dr. Goetz reported the results from the pulmonary function test, which indicated mixed restrictive and obstructive pulmonary disease that significantly improved with Albuterol. On 8/26/03, LabCorp America reported lab results (lab follow-up and review by Dr. Goetz on 9/4/03 and 9/30/03) indicated the CBC panel with differential was within normal range, the allergen profile for 13 molds were all negative, the hypersensitivity pneumonitis panel was all negative, the immunoglobulins IgA, IgE and IgG were normal but IgM was low, the Rheumatoid arthritis factor was within normal range and that antibodies for *Aspergillus niger* and *Aspergillus flavus* were negative. The results also indicated a Class IV allergy for shrimp. Dr. Goetz diagnosed Ms. Smith with new onset asthma that developed one year ago, perennial and seasonal allergic rhinitis, low IgM, shrimp intolerance, multiple medication intolerances (Bactrim, Erythromycin, and Prednisone), and reported that Ms. Smith’s work environment was associated with increases in upper and lower respiratory symptoms, including asthma, restrictive pulmonary disease, and rhinitis. Dr. Goetz suggested hypersensitivity pneumonitis as one possible mechanism for the patient’s respiratory symptoms. This was not confirmed by follow-up testing.^{40,41}

Pulmonary function tests reported by Dr. Goetz at the Exemplar Allergy and Asthma Clinic on 9/30/03, 12/23/03, and 2/1/05 indicated flow volumes close to 100% predicted.⁴² Dr. Goetz reported that Ms. Smith had boggy or pink turbinates on 8/26/03, 9/30/03, 10/23/03, and 12/23/03. Ms. Smith’s turbinates were reportedly not enlarged on 2/1/05. Dr. Goetz diagnosed Ms. Smith with possible chronic sinusitis on 9/30/03. A CT scan of

³⁹ Medical Record of Linda Smith: Davis Memorial Hospital, 6/6/03(000571)

⁴⁰ Medical Record of Linda Smith: David Goetz, MD, Exemplar Allergy and Asthma, 8/26/03 (000580-583)

⁴¹ Medical Record of Linda Smith: Laboratory Corp. of America, 8/26/03 (000573)

⁴² Pulmonary Function Test of Linda Smith: Exemplar Allergy Clinic, 9/30/03 (000568); 12/23/03 (000587); 2/1/05(000590)

Ms. Smith's sinuses on 10/08/03 found minimal soft tissue density at the left maxillary sinus may represent chronic sinusitis. Ms. Smith repeatedly had low IgM levels on numerous occasions.⁴³

Are molds and mycotoxins in the office environment capable of causing the claimed adverse effects?

For mycotoxin exposure to be considered the possible cause of any health effect, a mycotoxin capable of causing that health effect must be present. No sample results show that mycotoxins were present at the DHHR office. Additionally, the following health effects alleged by the plaintiffs have not been shown to be caused by exposure to mycotoxins of any kind under any circumstances.

- *Inhalation of mycotoxins does not cause **allergies to various insects, plants, and dusts**.* I conducted an exhaustive search of the scientific literature and was unable to find any peer-reviewed literature showing that inhalation of mycotoxins in an indoor environment causes allergies to various insects, plants, and dust.
- *Inhalation of mycotoxins does not cause **fatigue or body aches**.* I conducted an exhaustive search of the scientific literature and was unable to find any peer-reviewed literature showing that inhalation of mycotoxins in an indoor environment causes fatigue or body aches.
- *Inhalation of mycotoxins does not cause **breathing problems or respiratory difficulties** (allergic rhinitis, asthma, bronchitis, pharyngitis, cough, postnasal drip, stuffiness, congestion, sinus infection, sinus irritation, sinus pressure, chest tightness or pain, shortness of breath, or wheezing).* I conducted an exhaustive search of the scientific literature and was unable to find any peer-reviewed literature showing that inhalation of mycotoxins in an indoor environment causes breathing problems or respiratory difficulties. The Institute of Medicine (IOM) and the American Academy of Allergy, Asthma and Immunology (AAAAI) have concluded that damp indoor environments and molds or other agents in the environment are associated with some upper and lower respiratory symptoms, including exacerbation of existing asthma and allergies. However, both the IOM and the AAAAI found the scientific evidence was not adequate to conclude that mold can cause these conditions.⁴⁴
- *Inhalation of mycotoxins does not cause **skin problems** (irritation, itching, rash, dryness, erythema, discoloration).* I conducted an exhaustive search of the

⁴³ Medical Record of Linda Smith: David Goetz, MD, Exemplar Allergy and Asthma, 8/26/03 (000580-583); 9/30/03 (000568); 10/23/03 (000586); 12/23/03 (000587); 2/1/05 (000590)

⁴⁴ AAAAI . Position Paper -- The medical effects of mold exposure. J Allergy Clin Immunol 117(2), 326-333. 2006. ; Assoulin-Dayana, Y., Leong, A., Shoenfeld, Y., and Gershwin, M. E. Studies of sick building syndrome. IV. Mycotoxicosis. J Asthma 39(3), 191-201. 2002. ; Bardana, E. J., Jr. Indoor air quality and health -- Does fungal contamination play a significant role? Immunol Allergy Clin North Am 23(2), 291-309. 2003. ; IOM (04). Damp Indoor Spaces and Health. Institute of Medicine (IOM), National Academy Press, Washington, DC.

scientific literature and was unable to find any peer-reviewed literature showing that inhalation of mycotoxins in an indoor environment causes skin problems.

- *Inhalation of mycotoxins does not cause **pain** (facial, neck).* I conducted an exhaustive search of the scientific literature and was unable to find any peer-reviewed literature showing that inhalation of mycotoxins in an indoor environment causes pain.
- *Inhalation of mycotoxins does not cause **ocular problems** (eye itching, irritation, and burning; blurry vision).* I conducted an exhaustive search of the scientific literature and was unable to find any peer-reviewed literature showing that inhalation of mycotoxins in an indoor environment causes ocular problems.
- *Inhalation of mycotoxins does not cause **nausea**.* I conducted an exhaustive search of the scientific literature and was unable to find any peer-reviewed literature showing that inhalation of mycotoxins in an indoor environment causes nausea.
- *Inhalation of mycotoxins does not cause **headache**.* I conducted an exhaustive search of the scientific literature and was unable to find any peer-reviewed literature showing that inhalation of mycotoxins in an indoor environment causes headache.
- *Inhalation of mycotoxins does not cause **muscle cramps**.* I conducted an exhaustive search of the scientific literature and was unable to find any peer-reviewed literature showing that inhalation of mycotoxins in an indoor environment causes muscle cramps.
- *Inhalation of mycotoxins does not cause **poor memory and concentration**.* I conducted an exhaustive search of the scientific literature and was unable to find any peer-reviewed literature showing that inhalation of mycotoxins in an indoor environment causes poor memory and concentration.
- *Inhalation of mycotoxins does not cause **yeast infections**.* I conducted an exhaustive search of the scientific literature and was unable to find any peer-reviewed literature showing that inhalation of mycotoxins in an indoor environment causes yeast infections.
- *Inhalation of mycotoxins does not cause **face, ear, throat, nose, or mouth irritation/soreness/infection** (burning, tingling, or blistering).* I conducted an exhaustive search of the scientific literature and was unable to find any peer-reviewed literature showing that inhalation of mycotoxins in an indoor environment causes face, ear, throat, nose, or mouth irritation/soreness/infection.
- *Inhalation of mycotoxins does not cause **dizziness**.* I conducted an exhaustive search of the scientific literature and was unable to find any peer-reviewed literature showing that inhalation of mycotoxins in an indoor environment causes dizziness.
- *Inhalation of mycotoxins does not cause **emotional symptoms**.* I conducted an exhaustive search of the scientific literature and was unable to find any peer-reviewed literature showing that inhalation of mycotoxins in an indoor environment causes emotional symptoms.
- *Inhalation of mycotoxins does not cause **dryness** (eyes, mouth, and skin).* I conducted an exhaustive search of the scientific literature and was unable to find

any peer-reviewed literature showing that inhalation of mycotoxins in an indoor environment causes dryness.

I am a co-author of the American College of Occupational & Environmental Medicine Evidence-Based Position Statement entitled: Adverse Human Health Effects Associated with Molds in the Indoor Environment which represents the current medical position of the American College of Occupational and Environmental Medicine (ACOEM) as to the issue of alleged health effects of indoor mold. This position can be summarized as follows:

- Mold growth in the home, school, or office environments should not be tolerated because mold physically destroys the building materials on which it grows, mold growth is unsightly and may produce offensive odors, and mold is likely to sensitize and produce allergic responses in allergic individuals.
- Except for persons with severely impaired immune systems, indoor mold is not a source of fungal infections.
- Current scientific evidence does not support the proposition that human health has been adversely affected by inhaled mycotoxins in home, school, or office environments.

Additionally, I direct regular searches of the scientific literature for research and reviews investigating possible effects of mycotoxin inhalation on human health effects, and I personally read and review relevant literature. Most independent researchers have reached the conclusion that exposure to mycotoxins in residential, office, or school environments has not caused adverse effects in occupants.

- "...the current literature does not provide compelling evidence that exposure at levels expected in most mold-contaminated indoor environments is likely to result in measurable health effects."⁴⁵
- "The review led to the conclusion that the primary result from fungal exposure is allergic disease, and that the evidence for inhalation disease resulting from mycotoxin exposure in residential and office settings is extremely weak."⁴⁶
- "The literature review indicates that currently there is inadequate evidence supporting a causal relationship between symptoms or illness among building occupants and exposure to mycotoxins."⁴⁷
- "The current public concern for adverse health effects from inhalation of *Stachybotrys* spores in water-damaged buildings is not supported by published reports in the medical literature."⁴⁸

⁴⁵ Robbins, C. A., Swenson, L. J., Nealley, M. L., Gots, R. E., and Kelman, B. J. Health effects of mycotoxins in indoor air: a critical review. *Appl Occup Environ Hyg* 15(10), 773-784. 2000.

⁴⁶ Burge, H.A. (2001). *loc. cit.*

⁴⁷ Page, E. H. and Trout, D. B. The role of *Stachybotrys* mycotoxins in building-related illness. *American Industrial Hygiene Association Journal* 62(5), 644-648. 2001.

⁴⁸ Terr, A. I. *Stachybotrys*: relevance to human disease. *Ann Allergy Asthma Immunol* 87(6 Suppl 3), 57-63. 2001.

- “Although exposure to molds can produce significant mucosal irritation, there are very few data to suggest long-term ill effects. More importantly, there is no evidence in humans that mold exposure leads to nonmucosal pathology.”⁴⁹
- “There is no scientific evidence that *Stachybotrys* or other fungal species detected in indoor air or present on building materials cause brain damage.”⁵⁰
- “Toxic-mold fears have precipitated a spate of lawsuits. ... Unfortunately, much of the evidence is conjectural. Mycotoxins and other microbial products have been implicated as causative agents, but the range of symptoms attributed to toxic molds exceeds what can be explained rationally in terms of toxicological mechanisms.”⁵¹
- “... I have reviewed the literature concerning *Stachybotrys chartarum* and have not found scientific data to support the current public concern about health effects.”⁵²
- “... specific human toxicity due to inhaled fungal toxins has not been scientifically established.” and “Specific human toxicity due to inhaled mycotoxins is not well understood, and the likelihood that sufficient mycotoxins are airborne despite visible indoor mold remains unproven and controversial.”⁵³
- “...we have not found supportive evidence for serious illness due to *Stachybotrys* exposure in the contemporary environment.”⁵⁴
- “At present there is no scientific basis for claiming that individuals have suffered mental and emotional injuries by inhalation of mold, mold spores or mold metabolites, including mycotoxins in residential or office environments. To the extent that experts express conclusions that mold inhalation in residences or offices caused mental or emotional injuries or brain injury, their opinions are speculation, possibilities, and guesses.”⁵⁵
- “Currently, there is no supportive evidence to imply that inhaling mold or mycotoxins in indoor environments is responsible for any serious health effects other than transient irritation and allergies in immunocompetent individuals.”⁵⁶
- “The current model illustrates that delivery of mycotoxins via inhalation of mold spores is inefficient and suggests that mycotoxin intoxication does not follow inhalational mold spore exposure in indoor environments due to the requirement for extremely high airborne spore levels and extended periods of exposure. The comparison data indicate that it is highly unlikely that the dose of mycotoxin received in an indoor home, office, or school environment could approach levels

⁴⁹ Assoulin-Dayana, Y. et al. 2002. *loc. cit.*

⁵⁰ Bardana, E.J., Jr. 2003. *loc. cit.*

⁵¹ Bennett, J. W. and Klich, M. Mycotoxins. Clin Microbiol Rev 16(3), 497-516. 2003.

⁵² Chapman, J. A. *Stachybotrys chartarum* (*chartarum* = *atra* = *alternans*) and other problems caused by allergenic fungi. Allergy Asthma Proc 24(1), 1-7. 2003.

⁵³ Fung, F. and Hughson, W. G. Health effects of indoor fungal bioaerosol exposure. Appl Occup Environ Hyg 18(7), 535-544. 2003.

⁵⁴ Kuhn, D. M. and Ghannoum, M. A. Indoor mold, toxigenic fungi, and *Stachybotrys chartarum*: infectious disease perspective. Clin Microbiol Rev 16(1), 144-172. 2003.

⁵⁵ Lees-Haley, P. R. Toxic mold and mycotoxins in neurotoxicity cases: *Stachybotrys*, *Fusarium*, *Trichoderma*, *Aspergillus*, *Penicillium*, *Cladosporium*, *Alternaria*, *Trichothecenes*. Psychol Rep 93(2), 561-584. 2003.

⁵⁶ Fung, F. and Clark, R.F. 2004. *loc. cit.*

that would produce an acute toxic response, even under the extreme conditions modeled. Under the exposure conditions commonly encountered in a visibly moldy indoor environment, the potential for inhaling a toxic dose of mycotoxins is remote.”⁵⁷

- “There is no current body of clinical data defining a disease or pathology in those who claim illness from indoor mold growth because of water intrusion.”⁵⁸

Notably, no learned body has reached the conclusion that exposure to mycotoxins in residential, office, or school environments has caused adverse effects in occupants:

- “The reviews led CDC to conclude that a possible association between acute pulmonary hemorrhage/hemosiderosis in infants and exposure to molds, specifically *Stachybotrys atra*, was not proven.”⁵⁹
- “After reviewing available data, the council has concluded that public concern for adverse health effects from inhalation of *Stachybotrys* spores in water-damaged buildings is generally not supported by published reports in medical literature.” and “...the proposition that molds in indoor environments may lead to adverse health effects through mechanisms other than infection and allergic/immunologic reactions is an untested impression” and “Adverse health effects from inhalation of *Stachybotrys* spores in water-damaged buildings is not supported by available peer-reviewed reports in medical literature.”⁶⁰
- “Current scientific evidence does not support the proposition that human health has been adversely affected by inhaled mycotoxins in the home, school, or office environment.”⁶¹
- “The occurrence of mold-related toxicity (mycotoxicosis) from exposure to inhaled mycotoxins in non-occupational settings is not supported by the current data, and its occurrence is improbable.”⁶²
- “In recent years, increased concern has arisen about exposure to specific molds that produce substances called mycotoxins. Health effects related to mycotoxins are generally related to ingestion of large quantities of fungal-contaminated material. No conclusive evidence exists of a link between indoor exposure to airborne mycotoxin and human illness.”⁶³

⁵⁷ Kelman, B. J., Robbins, C. A., Swenson, L. J., and Hardin, B. D. Risk from inhaled mycotoxins in indoor office and residential environments. *Int J Toxicol* 23(1), 3-10. 2004.

⁵⁸ Terr, A. I. Are indoor molds causing a new disease? *J Allergy Clin Immunol* 113(2), 221-226. 2004.

⁵⁹ CDC . Update: pulmonary hemorrhage/hemosiderosis among infants--Cleveland, Ohio, 1993-1996. *MMWR Morb Mortal Wkly Rep* 49(9), 180-184. 2000.

⁶⁰ Texas Medical Association, Council on Scientific Affairs . Black mold and human illness. Texas Medical Association . 2002.

⁶¹ American College of Occupational and Environmental Medicine ACOEM . Evidence-Based Statement -- Adverse human health effects associated with molds in the indoor environment. *J Occup Environ Med* 45(5), 470-478. 2003.

⁶² AAAAI. 2006. *loc. cit.*

⁶³ CDC . Mold prevention strategies and possible health effects in the aftermath of hurricanes and major floods. *MMWR Morb Mortal Wkly Rep* 55(RR-8), 1-27. 2006.

In an extensive analysis, the Institute of Medicine was unable to conclude that any adverse health outcomes are caused by the presence of mold or other agents in damp indoor environments. The Institute did find sufficient evidence to conclude that there is an association between mold or damp indoor environments and certain symptoms (upper respiratory (nasal and throat) tract symptoms, cough, hypersensitivity pneumonitis in susceptible persons, wheeze, and asthma symptoms in sensitized persons), but the Institute makes it clear that “associated with” does not mean “caused by.” The Institute also found that the evidence is not sufficient to show even an association between the presence of mold or other agents in damp indoor environments and any other symptom.⁶⁴ All of the Institute’s findings are summarized in Appendix B.

Subsequent to the 2004 Institute of Medicine (IOM) report, two medical societies produced position statements in 2006 dealing with the health effects of exposure to moldy indoor environments. With the advantage of an additional two years of scientific investigations, conclusions reached by the American Academy of Allergy Asthma and Immunology (AAAAI)⁶⁵ and the American College of Medical Toxicology (ACMT)⁶⁶ were in complete agreement with the earlier positions taken by the ACOEM and IOM. The AAAAI and ACMT both expressed agreement with the ACOEM and IOM statements and both reiterated that indoor molds may exacerbate pre-existing allergies but are not the source of fungal infections. With respect to health hazards attributable to mycotoxins from indoor molds, the AAAAI concluded that “The occurrence of mold-related toxicity (mycotoxicosis) from exposure to inhaled mycotoxins in non-occupational settings is not supported by the current data, and its occurrence is improbable.”⁶⁷ Similarly, with respect to mycotoxins indoors the ACMT concluded that “... the available scientific evidence does not provide any compelling data to conclude that they pose significant health risks via inhalation in these settings. The risks from inhalation exposure are minimal in comparison to other sources and pathways, including the diet, which in themselves are rarely of health consequence in the United States.”⁶⁸

Are volatile organic compounds (VOCs) capable of causing the claimed adverse effects?

At sufficiently high levels and durations of exposure, volatile organic compounds (VOCs) have the potential to cause some of the health effects claimed by the plaintiffs. For example, common health problems caused by VOCs include eye, nose, or throat irritation

⁶⁴ IOM. 2004. *loc cit.*

⁶⁵ AAAAI. 2006. *loc. cit.*

⁶⁶ ACMT. 2006. *loc. cit.*

⁶⁷ AAAAI. 2006. *loc. cit.*

⁶⁸ ACMT. 2006. *loc. cit.*

(e.g., burning or tingling sensations), respiratory irritation, shortness of breath, chest tightness, wheezing, rhinitis, nasal congestion, headaches, nausea, vomiting, fatigue, dizziness, allergic skin reaction, rash, pruritus, and epistaxis.⁶⁹ However, all air sampling results for VOCs, including formaldehyde, collected by MSES Consultants and by NIOSH were well below established criteria levels or the level of detection.^{70,71}

Environmental Surveys

According to environmental survey results, all temperature and humidity determinations were in the recommended comfort range and all carbon monoxide determinations were low—well below the occupational exposure limit—indicating no source of combustion gases. Carbon dioxide levels were also below recommendations (with two minor excursions on 4/30/03 following high occupancy of the spaces sampled) indicating adequate fresh air was being supplied. Finally, all airborne mold measurements found similar distributions of genera indoors and outdoors, with airborne concentrations indoors well below those outdoors.^{72,73,74,75} This series of extensive environmental surveys consistently found that the Webster Springs offices of the DHHR were neither damp nor moldy.

c. Did the plaintiffs have an opportunity for contact with the chemicals, and if so, did the exposure result in a sufficient dose to cause the claimed adverse effects?

Mold and Mycotoxins

As previously discussed in this report, there is no evidence that mycotoxins were ever present at the DHHR office. If mycotoxins were present, they would have to gain access to the biological target (here, the plaintiffs) in sufficient quantities to cause an effect.

The dose-response relationship is the most fundamental and pervasive concept in toxicology and an understanding of this relationship is essential for the study of toxic materials. The fundamental basis of the quantitative relationships between exposure to an

⁶⁹ EPA (94). Indoor air quality -- an introduction for health professionals, GPO Publication No. 1994-523-217/81322, 1994. Environmental Protection Agency (EPA).

⁷⁰ Report of Findings, Follow-Up Investigation of Webster Springs Department of Health and Human Resources by MSES Consultants, dated 6/2/03 (inspection 4/30/03 and 5/9/03)

⁷¹ NIOSH Health Hazard Evaluation Report, dated March 2006 (inspection 9/03 and 4/04)

⁷² Department of Health and Human Resources Indoor Air Quality Evaluation of DHHR Office Webster Springs, Report dated 8/2/02 (inspection 6/27/02)

⁷³ Report of Findings, Indoor Air Quality Investigation Department of Health and Human Resources by MSES Consultants, dated 10/22/02 (inspection 10/2/02)

⁷⁴ Report of Findings, Follow-Up Investigation of Webster Springs Department of Health and Human Resources by MSES Consultants, dated 6/2/03 (inspection 4/30/03 and 5/9/03)

⁷⁵ NIOSH Health Hazard Evaluation Report, dated March 2006 (inspection 9/03 and 4/04)

agent and the incidence of an adverse response is the dose-response assessment.⁷⁶ All chemicals have toxic properties that become apparent as increasing quantities are consumed or absorbed. It follows that there may be “safe” levels of exposure to even the most toxic substances.⁷⁷

A particularly important term in toxicology is threshold, which means the level of exposure at which an effect is first observed.⁷⁸ The erroneous opinion that exposure to “toxic chemicals” at any dose produces deleterious effects abounds in the lay public and is prevalent in the medical profession. The fact that dose defines toxicity for all chemicals has been recognized for centuries.⁷⁹

Exposure-response relationships are among the most important criteria for inferring causality.⁸⁰ Characterizing the dose-response relationship involves understanding the importance of the intensity of exposure, the concentration \times time relationship, whether a chemical has a threshold, and the shape of the dose-response curve. The metabolism of a chemical at different doses, its persistence over time, and an estimate of the similarities in disposition of a chemical between humans and animals are also important aspects of a dose-response evaluation.⁸¹

Neither documented exposure nor odor detection necessarily dictates adverse responses to any chemical. To paraphrase an overused but often ignored truism: the dose of a chemical determines whether that chemical is toxic or nontoxic. Appreciation and application of this basic tenet of toxicology, the dose-response relationship, are necessary when objectively evaluating chemically mediated effects.⁸²

Mycotoxins are not volatile, and do not evaporate from the mold spore, colony, or growth substrate.⁸³ Therefore, if mycotoxins are present, they can gain access to the biological target (the plaintiffs) only by being carried on and inhaled with spores.

In order to determine whether sufficient quantities of mycotoxins (if present) could have gained access to the biological target, I used a published, peer-reviewed methodology⁸⁴ to

⁷⁶ Klaassen, C. D. (2001). McGraw-Hill.

⁷⁷ Zenz, C. (1994). Moseby-Year Book, Inc..

⁷⁸ Hayes, A. W. (1994). Raven Press.; Schiefer, H. B. Mycotoxins in indoor air: a critical toxicological viewpoint. *Indoor Air* '90 , 167-172. 1990.

⁷⁹ Montgomery, M. R. and Reasor, M. J. A toxicologic approach for evaluating cases of sick building syndrome or multiple chemical sensitivity. *J Allergy Clin Immunol* 94(2 Pt 2), 371-375. 1994.

⁸⁰ Clayton, G. D. and Clayton, F. E. (1991). John Wiley & Sons, Inc..

⁸¹ Hayes, A. W. (1994). *loc. cit.*

⁸² Hayes, A. W. (1994). *loc. cit.*; Schiefer, H.B. 1990. *loc. cit.*

⁸³ Schiefer, H.B. 1990. *loc. cit.*; WHO (90). Selected mycotoxins: ochratoxins, trichothecenes, ergot, Environmental Health Criteria 105. World Health Organization (WHO), Geneva, Switzerland.

⁸⁴ Kelman, B.J. et al. 2004. *loc. cit.*

estimate the highest possible mycotoxin exposure inside the subject property. To calculate the maximum dose that is possible from the plaintiffs' residential environment, I used the following factors:

- the highest measured airborne fungal count in the office: 386 spores/m³ in the cubicle near the computer room in spore trap sampling conducted by NIOSH during sampling conducted on 9/11/2003. The total spore count outside the building on the same day was 12,608 spores/m³.
- the presence of mycotoxins was assumed at the highest concentrations per spore that have been reported in the scientific literature
- the average breathing rate of each individual (average breathing rates provided in the EPA Exposure Factors Handbook⁸⁵)
 - 0.47 cubic meters per hour - adult female
- 100% retention of inhaled spores with 100% availability of mycotoxins was assumed
- exposure was assumed for a 24-hour occupancy
- the lowest reported body weight of the exposed individuals.
 - 124 lbs Reta Lorene Boone⁸⁶
 - 181 lbs Elizabeth Cochran⁸⁷
 - 200 lbs Sally Conley⁸⁸
 - 141 lbs Mary Hall⁸⁹
 - 249 lbs Evelyn Jordan⁹⁰
 - 136 lbs Arletta Mathes⁹¹
 - unknown body weight Margarette McCourt. (EPA Exposure Factors Handbook average adult female body weight is 65.4 kg or 144 lbs)
 - 190 lbs Joy Skeens⁹²
 - 158 lbs Linda Smith⁹³

⁸⁵ EPA (97). Exposure Factors Handbook, EPA/600/P-95/002Fa. Office of Research and Development, US Environmental Protection Agency (EPA), Washington, DC 20460, Washington, DC.

⁸⁶ Medical records of Reta Lorene Boone: D. Gaziano, MD, Chest Medical Services, Inc. 7/21/05 (000592-599)

⁸⁷ Medical records of Elizabeth Cochran: Joseph E Grady II, MD, CIME, Tri-State Occupational Medicine, Inc. 8/10/05 (000009-013)

⁸⁸ Medical records of Sally Conley: Bruce Guberman, MD Tri-State Occupational Medicine, Inc. 9/21/05 (000530-534)

⁸⁹ Medical records of Mary Hall: Joseph E Grady II, MD, CIME, Tri-State Occupational Medicine, Inc. 5/4/05

⁹⁰ Medical records of Evelyn Jordan: Bruce Guberman, MD Tri-State Occupational Medicine, Inc. 9/21/05 (000060-065)

⁹¹ Medical records of Arletta Mathes: Joseph E Grady II, MD, CIME, Tri-State Occupational Medicine, Inc. 4/12/06

⁹² Medical records of Joy Skeens: Bruce Guberman, MD Tri-State Occupational Medicine, Inc. 8/18/05 (RBM 0440-441)

⁹³ Medical records of Linda Smith: David Goetz, MD Exemplar Allergy and Asthma 8/26/03 (000580-583)

Each factor represents a condition far in excess of any condition actually pertaining to the plaintiffs so that resulting calculations are *certain* to over-estimate actual exposure.

In order to evaluate whether there is a possibility of adverse effects, I compared the maximum possible dose that the plaintiffs could have received from the indoor environment to the lowest dose that is known to produce an effect in animals. These calculations (see Appendices C to E) show that even with a 24-hour exposure to the highest spore concentration reported inside the DHHR office (386 spores/m³), the plaintiffs could not be exposed to the lowest reported toxic dose of any of the modeled mycotoxins (fumitremorgens, satratoxins, and trichoverrols), and that the maximum possible dose of aflatoxin B1 could not exceed the daily dietary dose permitted by US FDA food regulations. Therefore, it is clear that if any mycotoxins were present, exposure could not have been sufficient to cause any injuries to the plaintiffs.

VOCs

Air sampling results for VOCs collected on May 9, 2003 by MSES Consultants identified the presence of 10 compounds; however, all of the concentrations were well below established criteria levels published by OSHA and NIOSH presented in Appendix F.⁹⁴ Therefore, exposure could not have been sufficient to cause any injuries to the plaintiffs.

d. Did exposure to the chemicals precede the claimed adverse effects?

The Department of Health and Human Resources (DHHR) leased a portion of the premises located at 110 North Main Street, suite 201, Webster Springs, West Virginia beginning in 1993 or 1994.⁹⁵ In 2000, the DHHR space was renovated.⁹⁶ In the spring of 2002, complaints of runny eyes and noses began.⁹⁷ Medical records for the plaintiffs for the period preceding 2002 were not provided for my review; however, some reported medical histories in the records and IME reports indicate long-standing prior conditions.

CONCLUSIONS

Based on a review of the records provided to me in this matter, and a review of the literature, my opinions are as follows:

⁹⁴ Report of Findings, Follow-Up Investigation of Webster Springs Department of Health and Human Resources by MSES Consultants, dated 6/2/03 (inspection 4/30/03 and 5/09/03)

⁹⁵ Deposition of Bill Adamy (93:1-93:23); Complaint

⁹⁶ Deposition of Bill Adamy (123:13-124:3)

⁹⁷ Deposition of Bill Adamy (5:4-5:16)

- Mold and mold spores are ubiquitous, and the maintenance of a mold-free residential environment is not possible.
- There are no data showing that any mycotoxins were ever present in the indoor air at 110 North Main Street, Suite 201.
- There are no data showing that there could have been a sufficient amount of mycotoxin present to cause any injury to the plaintiffs. Furthermore, the above review of toxicity of various mycotoxins indicates that it is nearly impossible to inhale sufficient mycotoxins in an indoor environment to produce toxic effects.
- Inhalation of molds or mycotoxins in an indoor environment is not known to cause any of health effects claims by the plaintiffs.
- There are no data showing that there could have been a sufficient amount of VOCs present to cause any injury to the plaintiffs.
- Therefore, it is my opinion that none of the injuries claimed by the plaintiffs could have been caused by mycotoxins, VOCs, or other environmental conditions at the DHHR office.

I hold all of the foregoing opinions to a reasonable degree of scientific certainty. This report is based on the materials received and analyzed by me to date. Should additional information become available, I reserve the right to amend my opinions accordingly.

Bryan D. Hardin, PhD, Fellow, A.T.S.
Principal

Date

Enclosures: Appendices A-F

Appendix A: Dr. Hardin – CV

Appendix B: Institute of Medicine Findings

Appendix C: Known Effects Levels

Appendix D: Known Effects Levels

Appendix E: Regulatory Levels

Appendix F: VOC Air Sampling